



**CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH**

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Audrey Tayse Haynes
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To: All Kentucky Vaccine Program Providers

From: Laura C. Harrod, MS Ed
Kentucky Vaccine Accountability Section Coordinator

Date: June 16, 2015

Subject: Restitution Flow Chart and Soon to Expire Vaccines

The updated Kentucky Immunization Program (KIP) Restitution Policy was sent to providers on December 1, 2014. We designed a flow chart to demonstrate when restitution is required for KIP vaccines. (*Enclosed*)

Please follow the flow chart to determine if you will be required to pay back dose for dose vaccine lost, wasted, or expired. KIP Staff will contact your Primary Vaccine for Children (VFC) Contact once we receive your Return and Adjustment form to discuss the steps for repayment.

Procedures are:

1. Return and Adjustment (R&A) Form is sent to KIP with the order form. If there is a large vaccine loss or a storage and handling issue occurred, the R&A Form should be submitted immediately. Do not wait until time to order! In some instances, a vaccine order will not be placed due to storage and handling issues.
2. The Vaccine Accountability Section (VAS) receives the R&A form and contacts your VFC Primary Contact to discuss restitution. Typically we require a dose for dose replacement. When replacement includes influenza partial packages and/or multi dose vials, replacement is based on KIP vaccine costs and not dose for dose. We attempt to be conservative for the providers.

NOTE: Do not order replacement vaccines until we have given approval and discussed repayment.

3. The Provider Site places the replacement vaccines order, receives the order, and stocks the replacement vaccines. Replacement vaccine packing slips should be sent to VAS at 502/696-4923 or dph.kvp@ky.gov. These replacement vaccines must be placed in the VFC section of the storage unit, stored appropriately, and administered to VFC eligible children.
4. VAS will send a copy of the replacement vaccine packing slip to your Field Staff Representative. The Field Staff will visit your site to access vaccine storage and compare the packing slips to the VFC vaccines. If vaccines have been administered your office will be required to show the Field Staff the lot numbers used for VFC eligible children.
5. Once all vaccines are paid back to KIP; your clinic will be able to receive VFC vaccines again and may resume the ordering process.

Restitution Flow Chart

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You are required to report "soon to expire" doses of KIP vaccines. If you have on hand KIP vaccines that will expire in three months (90 days) you should either send an email to dph.kvp@ky.gov or fax the enclosed optional form to 502/696-4923.

KIP recognizes that you may administer the vaccine in the 90 days timeframe. If you administer the vaccine previously reported as "soon to expire", no additional paperwork will be needed. If the vaccine is not administered and expires, a Return and Adjustment Form must be submitted as customary.

Contact VAS for further questions at 502/564-4478, fax line 502/696-4923 or email at dph.kvp@ky.gov.

VAS staff contact information:

Jane Payne at Jane.Payne@ky.gov for PINs that start with FQ, RH, OP and CC. Phone extension is 4252.

Rita Lathrem at Rita.Lathrem@ky.gov, for PINs that start with H, adult and SC. Phone extension is 4258.

Clarissa Goode at Clarissa.Goode@ky.gov for PINs that start with D, 100 or 200. Phone extension is 4267.

Ida Taylor at Ida.Taylor@ky.gov, VAS Assistant Coordinator and influenza orders. Phone extension is 4268.

Laura Harrod at Laura.Harrod@ky.gov, VAS Coordinator. Phone extension is 4256.

Thank you.

Attachments: Restitution Policy from 12/1/14
Restitution Flow Chart 6/11/15
3 Months to Expire Optional Form 4/20/15

cc: Kraig Humbaugh, MD, MPH
Robert Brawley, MD, MPH, FSHEA
Margaret Jones, RN, BSN, BSEd
Jennifer Paulk

**Kentucky Immunization Program
Restitution Policy
Effective December 1, 2014**



Kentucky Public Health
Prevent. Promote. Protect.

Introduction: Vaccine quality is the shared responsibility of all parties from the time the vaccine is manufactured until administration. Accountability of vaccine inventory is an essential requirement of participation in the Kentucky Immunization Program (KIP). The KIP includes the federal Vaccines for Children (VFC) Program, federal vaccine purchased for outbreaks and special programs, and state purchased vaccines. Vaccines are costly and federal and state funds for vaccine purchases are limited. The Restitution Policy requires any KIP provider deemed negligent by the KIP in any loss of KIP supplied vaccines to replace the lost vaccine on a dose-for-dose basis. Proof of purchase must be submitted to the program within 90 days.

Definitions:

Expired vaccine: Any vaccine with an expiration date that has passed.

Spoiled vaccine: Any vaccine that is stored or transported outside of the limits of the approved cold chain procedures or any vaccine that has been pre-drawn and not used within acceptable time frames. Always consult with KIP before determining that vaccine is spoiled.

Lost vaccine: Any vaccine ordered but not delivered or not delivered in a timely manner by the commercial carrier or delivery service that result in lost and/or spoiled vaccine.

Vaccine that is determined to be expired, spoiled, lost, or otherwise unusable is considered "wasted vaccine."

Policy: As part of the enrollment process for KIP, providers agree to comply with KIP requirements for ordering, storage, handling, and accountability of vaccine. The Provider Agreement, states that providers agree to: "replace vaccine purchased with state and federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a dose-for-dose basis."

Beginning December 1, 2014 the provider will assume responsibility to replace wasted vaccine on a dose for dose basis within 90 days. There is a wide range of potential vaccine storage and handling issues that may result in wasted vaccine. The KIP will review each incident of wasted vaccine to determine whether restitution will be required. If restitution is required the practice will not receive additional KIP vaccine until replenishment with replacement vaccine is demonstrated and the problem that caused the wastage has been corrected.

Effective December 1, 2014

Situations Requiring Restitution: The following situations are examples of negligence that would lead to non-viable vaccine which may require restitution. This list is not exhaustive.

- Failure to rotate vaccine stock in order to use vaccine with the shortest expiration date first
- Failure to notify KIP a minimum of 90 days prior to vaccine expiration date
- Repeated waste of vaccine due to drawing up or preparing vaccine prior to patient screening
- Vaccine left out of the refrigerator or freezer resulting in vaccine reaching unacceptable temperatures
- Freezing vaccine that must be refrigerated
- Refrigerating vaccine that must be frozen
- Excessive ordering of vaccine that results in the expiration of vaccine before it can be used
- Provider staff failing to review, appropriately interpret and/or document refrigerator and/or freezer temperatures twice daily
- Vaccine that is considered spoiled due to temperature monitoring problems/errors
- Unplugged refrigerator/freezer unit or electrical breaker switched off for extended periods of time
- Failure to contact KIP when refrigerator or freezer malfunction results in temperature fluctuations
- Refrigerator or freezer malfunctions or power outages in which provider staff fails to follow their Emergency Vaccine Management Plan and/or fails to contact KIP
- Planned power outages in which provider staff fails to implement precautions to maintain appropriate storage of vaccine
- Vaccine received but unaccounted for in stock
- Transportation of vaccine inappropriately: unnecessary transportation of vaccine, transportation without KIP consent, and/or failure to appropriately maintain cold chain during transportation
- Failure to use single antigen vaccines or allowing single antigen vaccines to expire in favor of using combination vaccines
- Failure to notify KIP when provider's office will be closed for non-emergency situations i.e., holidays, trainings, parties, etc. KIP must be notified 3 weeks in advance of planned closing to prevent delivery of vaccines during this time
- Substantial vaccine wastage resulting from repeated or unresolved incidents from the list below of "Situation That Do Not Require Restitution"

Situations That Do Not Require Restitution: The following situations are examples of situations in which loss of vaccine would **NOT** require restitution. In these situations the provider practice is deemed to not be at fault. This list is not exhaustive.

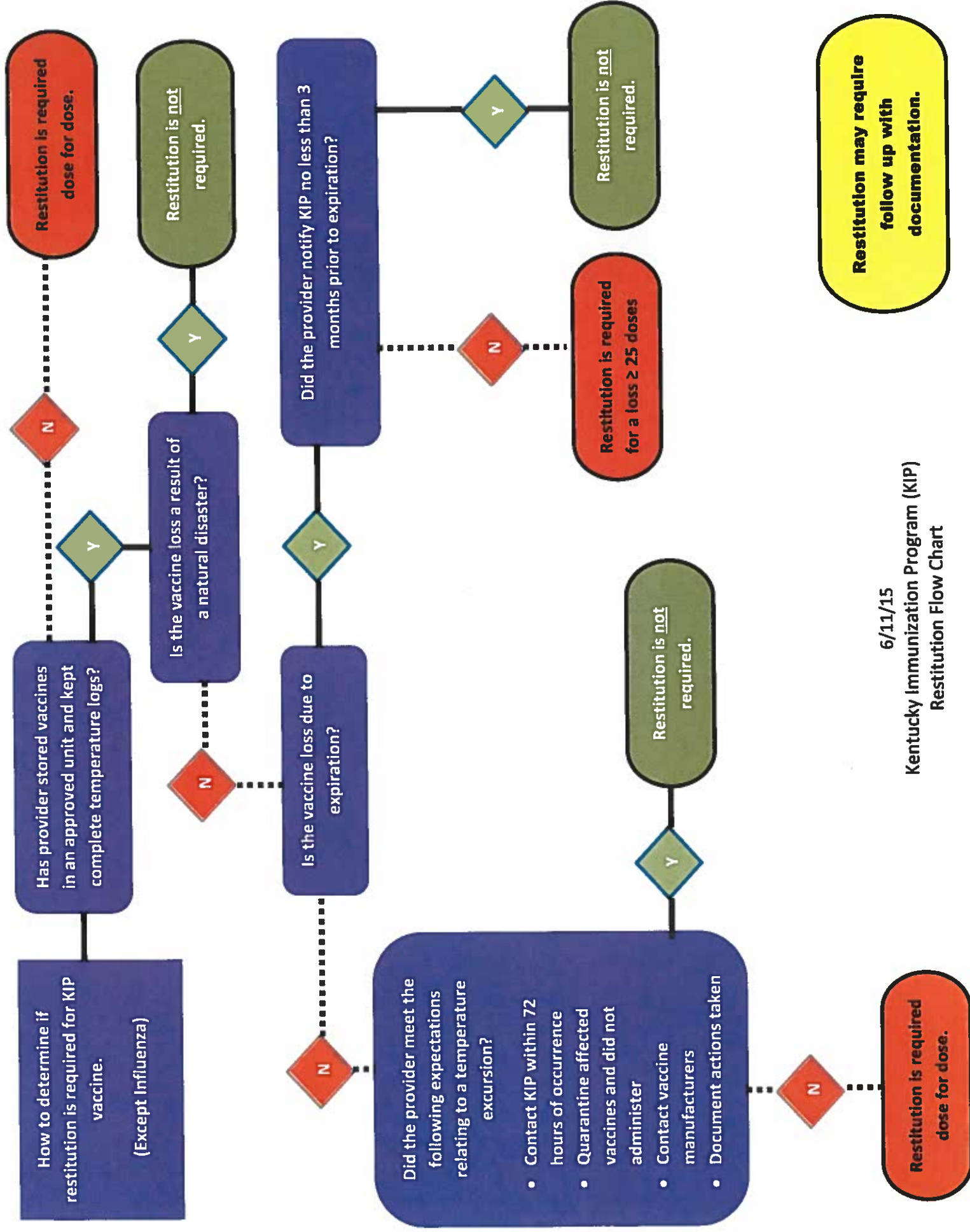
- Vaccine is damaged, improperly stored during transit, or not delivered in a timely manner by commercial carrier or delivery service.
- Provider staff moved vaccine to their back-up location as outlined in their Vaccine Management Plan, in anticipation of power storage or due to refrigerator or freezer malfunction and the back-up location experienced power outage or equipment malfunction.
- Power interruption or failure due to storms or other weather conditions.
- Unanticipated refrigerator or freezer failure that occurs overnight, during the weekend or during a period of time when the provider staff is not present.

- Partially used multi-dose vials of vaccine.
- A vial of vaccine that is accidentally dropped or broken by provider staff.
- Occasional instances of wasted vaccine due to provider staff error or last minute patient refusal.
- Expired vaccine the provider staff notified KIP about and redistribution made to another provider.
- Extraordinary situations not listed above which are deemed by KIP to be beyond the provider's control

Procedure for Restitution: Each incident reported will be reviewed on a case-by-case basis by KIP to determine whether restitution will be required or if extenuating circumstances exist.

- Call KIP if you suspect vaccine has been exposed to a situation that would deem it wasted.
- Fill out the Return and Adjustment Form (R&A) and fax it to (502) 696-4923. Keep a copy for your records and make a copy to send with wasted vaccines that are returned to McKesson Specialty Distribution.
- After the R&A Form is received by KIP, a return shipping label will be sent directly from McKesson Specialty Distribution to you in approximately 2-3 weeks.
- Once the shipping label is received, return the vaccine to McKesson Specialty Distribution without ice or gel packs but with "*filler*" so the vials will not break.
- If restitution is required, the provider will be asked to submit an invoice to KIP within 90 days showing they have purchased vaccine to replace the wasted vaccine. Providers should contact their insurance carrier to determine if there is coverage for lost vaccine.
- Failure to replace vaccine will result in a delay of future KIP vaccine orders.

Please contact KIP if you experience staff changes that impact vaccine storage and handling duties in the practice. Vaccine security depends on proper education and training. If you have any questions concerning this policy, please call KIP staff at (502) 564-4478.



KENTUCKY IMMUNIZATION PROGRAM
3 MONTHS TO EXPIRE *OPTIONAL* FORM
 275 EAST MAIN STREET, HS2E-B, FRANKFORT, KY 40621-0001
 Phone (502) 564-4478 / Fax (502) 696-4923 / Email: dph.kvp@ky.gov

Pin #: _____ **Phone:** _____ **Date:** _____

Facility Name: _____

Address: _____

Person Preparing Form: _____ **Is this adult or VFC?** _____

Please use this form to report your doses that will expire in the next 90 days (or 3 months). A determination for reimbursement of doses will be made AFTER the Return & Adjustment has been submitted.

Vaccine and NDC #	Lot #(s)	Expiration Date	Number of Doses
Vaccine			
NDC #			
Vaccine			
NDC #			
Vaccine			
NDC #			
Vaccine			
NDC #			
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